https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

ICS 11.040; 35.240.01
C 30

YY

Professional Standard of the People's Republic of China

YY/T 1752-2020

Basic data set of unique device identification database

医疗器械唯一标识数据库基本数据集

(English Translation)

Issue date: 2020-06-30 Implementation date: 2020-10-01

Issued by the National Medical Products Administration

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

Contents

Foreword i
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Abbreviations 1
5 Basic data subset categories of the unique device identification database 2
6 Description of data item 2
7 Data subset related to basic information of the unique device identification database 4
8 Data subset related to information of the unique device identifier coding institution 5
Annex A (Normative) Value range code table 24
Annex B (Normative) Description of location values 25
Bibliography 26

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

Foreword

ChinaStandards.net is in charge of this English translation. In case of any doubt about the English translation, the Chinese original shall be considered authoritative.

This standard is developed in accordance with the rules given in GB/T 1.1-2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This standard was proposed by the National Medical Products Administration.

This standard is under the jurisdiction of the National Medical Products Administration.

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

Basic data set of unique device identification database

1 Scope

This standard specifies the categories, data subsets and other related contents of basic data sets involved in the unique device identification database.

This standard is applicable to the construction of unique device identification database.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2260	*Codes for the administrative divisions of the People's Republic of China*
GB/T 7408	*Data elements and interchange formats - Information interchange - Representation of dates and times*
YY/T 1681	*Basic terms of unique device identification system*

3 Terms and definitions

For the purposes of this standard, the terms and definitions established in YY/T 1681 as well as the followings apply.

3.1
direct marking UDI-DI
marking that the medical device body is directly applied with the unique device identifier.

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

UDI: Unique Device Identifier

UDI-DI: Device Identifier

MR: Magnetic Resonance

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

5 Basic data subset categories of the unique device identification database

The basic data set of the unique device identification database mainly includes the basic information of the unique device identification database, contact information of medical device registrant/filer, and data subset of the information of the UDI coding institution. See Table 1 for specific categories.

Table 1 Basic data subset categories of the unique device identification database

S.N.	Data subset category	Data subset
1	Data subset related to basic information of the unique device identification database	Data subset of basic information of the unique device identification database
		Data subset of contact information of medical device registrant/filer
2	Data subset related to the information of the unique device identifier coding institution	Data subset of the information of the unique device identifier coding institution

6 Description of data item

6.1 Short name of data item

Initials of Chinese phonetic alphabets of Chinese names (ignoring symbols) of data items are used as field names in the construction of the unique device identification database. If there is a data item with the same short name in a data subset, the following treatment principle shall be followed: start with the first repeated short name, add two sequence numbers after the short name, and the sequence numbers will increase from 01.

6.2 Description of data source

The definition or purpose of the data item shall be described.

6.3 Data type

See Table 2 for symbols, characters or other types of data items.

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

Table 2 Data type

Data type	Description
Character type	Value represented in character form
Integer type	Integer value represented by numbers “0” to “9”.
Floating-point type	Real number represented by numbers "0" to "9"
Date type	Value represented in the form of YYYYMMDD, which conforms to GB/T 7408
Date-time type	Value represented by in the form of YYYYMMDDThhmmss, which conforms to GB/T 7408
Boolean type	Two and only two values indicating conditions, True/False
Binary system	Other data types that cannot be covered by the above types, such as image type, audio type, etc.

6.4 Representation format

The representation format of data item value specified from the business point of view, includes the maximum and/or minimum allowed character length, data item value, etc. See Table 3 for the meanings of characters used in the representation format of data items.

Table 3 Meaning of characters in the representation format

Representation format	Description
YYYYMMDDThhmmss	"YYYY" represents the year; "MM” represents the month; "DD" represents the date; "T" represents an identifier of time; "hh" represents the hour; "mm" represents the minute; "ss” represents the second. They can be combined according to the actual conditions.
i	Representing the number of characters
a	Representing an alphabetic character
n	Representing a numeric character
an	Representing alphabetic and numeric character
ai	Representing that the length is fixed to i alphabetic characters
ni	Representing that the length is fixed to i numeric characters
ani	Representing that the length is fixed to i letters and numeric characters
a..i	Representing that the length is up to i alphabetic characters
n..i	Representing that the length is up to i numeric characters
an..i	Representing that the length is up to i alphabetic and numeric characters
..ul	Text of indefinite length

6.5 Allowable value

There are two types of data item range in this part:

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

a) Enumerable value range: the value range specified by the list of allowable values, and each allowable value and its meaning shall be represented in pairs:

1) If there are fewer optional values (3 or less), they will be listed directly in the attribute of "Allowable Value".

2) If there are more optional values (more than 3), write the name of the value range code table in the attribute of "Allowable Value", and list the value range code table in the normative annex. If the code table is from a reference standard, the standard number shall be indicated.

b) Non-enumerable value range: the value range specified by the description; the allowable value within this value range shall be accurately described in the attribute of the "Allowable Value".

6.6 Constraint

It is a descriptor indicating whether a data item is selected. The descriptor is:

a) mandatory: it indicates that the data item must be selected;

b) optional: it indicates that the data item may be or may not be optional according to actual application;

c) mandatory if applicable: it indicates that the data item must be selected when the conditions defined in the constraint conditions described in the remarks are met.

7 Data subset related to basic information of the unique device identification database

7.1 Data subset of basic information of the unique device identification database

The data subset of basic information of the unique device identification database mainly includes: basic information of device identifier, basic information of device, information of package UDI-DI and its packaging level association, basic information of clinical use, etc. See Table 4 for details, in which:

a) data items 1 ~ 5 are basic information of device identifier;

b) data items 6 ~ 14 are basic information of device;

c) data items 15 ~ 17 are basic information of direct marking UDI-DI;

https://www.chinastandards.net/standard/YYT1752-2020.html

https://www.ChinaStandards.net -> Buy the full version pdf -> Delivered by sales@ChinaStandards.net

Bibliography

[1] YY/T 0987.1-2016 *Implants for surgery - Magnetic resonance compatibility - Part 1: Safety marking*

[2] CFDAB/T 0301.1-2014 *Basic data element of food and drug administration information - Part1: General principles*

[3] *Announcement of the National Medical Products Administration on Issuing the Rules for the unique device identifier system ([2019] No.66)*

[4] *Announcement of the China Food and Drug Administration on Publishing the Catalog of medical device classification ([2017] No.104)*

[5] *Notice of the National Medical Products Administration on Printing and Distributing In vitro diagnostic reagents classification subcatalogue (ShiYaoJianXieGuan [2013] No.242)*

[6] *Food and Drug Administration. GUDID-Data-Elements-Reference-Table [EB/OL]. (2019-06-24). https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/gudid-guidance*

https://www.chinastandards.net/standard/YYT1752-2020.html